

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 6/21/2011 have been fully considered but they are not persuasive.
2. Applicant argues that the combination of Palmaz and Casey do not suggest a plurality of openings that pass through the wall thicknesses composing the coincident peaks and the wall thicknesses composing the coincident valleys. This is not persuasive because Palmaz teaches openings that are present throughout the entire surface of the graft (see fig. 8A-C, also see pg. 3 line 18-pg. 4 line 19). Applicant's argument that Palmaz is limited to teaching openings only in the interstitial region is not persuasive because Palmaz is not limited to the web-stent embodiment which Applicant relies on (Applicant's remarks filed 6/21/2011 pg. 8 line –pg. 9 line 3). Palmaz teaches a graft with interstitial regions throughout the surface of the graft (fig. 8A-C).
3. Applicant argues that the graft of Casey is made from non-metallic material using a mechanical or fluid force to shape the graft on a mandrel. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Palmaz teaches metallic and pseudometallic materials and fabrication techniques. Casey is relied upon as a teaching reference for a specific pattern of undulations or corrugations. A person of ordinary skill in the art, looking to the combination of Palmaz and Casey would appreciate

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combination of the materials and manufacturing techniques of Palmaz with the specific pattern of Casey for the purpose of providing corrugations on a thin film graft.

Corrugations are desirable in order to impart flexibility to the graft.

4. Examiner has applied a new claim rejection under 35 USC section 112, first paragraph to address newly added claim language in claim 18 that reads: "the wall thicknesses of the coincident peaks is less than the wall thicknesses of the coincident valleys" The specification fails to describe a variable thickness between the peaks and the valleys of the graft.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe the wall thicknesses of the coincident peaks being less than the wall thicknesses of the coincident valleys, as required by the 6/21/2011 amendment to claim 18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims **1, 3, 13-14, 17-18, 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) (Palmaz) in view of Casey, II et al. (Pub. No.: US 2004/0019375) (Casey).
2. Palmaz teaches an implantable medical graft, comprising: a generally tubular body member comprising a film selected from the group consisting of metallic and pseudometallic materials (page 17, lines 1-7) and a plurality of microperforations disposed through the wall thickness of the graft (figs. 8A-C; pg. 3 line 18-pg. 4 line 19).
3. Palmaz suggests adding circumferential corrugations defined by a radially undulating pattern of wall segments disposed between longitudinally alternating radially extending peaks and valleys (fig. 2 and 10, and page 5, lines 16-19, specifically: "the plurality of structural members may be arranged . . . [as] single or plural elements which form a tubular diamond-like or undulating pattern, in which adjacent structural members are spaced apart from open regions or interstices between adjacent structural members"). Palmaz suggests that the circumferential corrugations are the same material as the surrounding "web" (pg. 6 lines 23-27).

However, this teaching from Palmaz is not described in sufficient detail to warrant the conclusion that Palmaz teaches continuous circumferential corrugations with radially extending peaks and valleys. Casey teaches a vascular graft structure with continuous circumferential corrugations having radially extending peaks and valleys (fig. 1 and 4B) resulting in a prosthetic graft with strong and flexible walls that has coincident peaks

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and valleys on the luminal and abluminal surfaces. Casey further teaches undulation-free sections (fig. 1, 4A-B). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the graft of Palmaz with areas of continuous circumferential undulations with radially extending peaks and valleys as suggested by Palmaz and specifically taught by Casey for the purpose of providing a strong and flexible graft wall. The need for flexibility is particularly relevant when designing for implantation within a curved vessel in the body or when providing a minimally invasive implantation technique. Palmaz teaches several methods of fabricating the disclosed stent/graft, including vacuum deposition and etching. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to combine a thin film deposited graft as taught by Palmaz with a specific undulating pattern as taught by Casey, since doing so would be an obvious modification to the graft shape Palmaz. The combination of Palmaz and Casey would be desirable in order to provide a strong yet flexible graft. Such a substitution of a known undulating pattern in the device of Palmaz would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

4. Palmaz teaches microperforations disposed through the wall segments (e.g. figs. 2-3 and 8A-C, page 12 lines 1-8). Palmaz teaches non-undulating circumferential regions (see fig. 3); Casey further teaches non-undulating circumferential regions (figs. 1-5). The Palmaz stent is made of a film of metallic material, including titanium, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon,

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magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof (pg. 17 lines 1-7).

5. With respect to claim 17, Palmaz in view of Casey teach the circumferential corrugations as claimed. The resultant combination would be fully capable of bending in excess of 180 degrees about the longitudinal axis, since Palmaz discloses thin film deposition, which results in a thin and flexible prosthesis, and Casey teaches the use of corrugations to increase flexibility (fig. 1). With respect to claim 18, Palmaz in view of Casey is explained supra. In addition, Palmaz teaches thin film deposition with a plurality of mechanisms to adjust the thickness of the device (col. 6 lines 9-21). This results in corrugations with variable thicknesses (fig. 7, for example).

6. Claims **2, 11-12, 15, 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) (hereafter, Palmaz) in view of Casey, II et al. (Pub. No.: US 2004/0019375)(hereafter, Casey) further in view of Chuter et al. (Pub. No.: US 2003/0176912)(hereafter, Chuter).

7. Palmaz in view of Casey is explained supra. Palmaz in view of Casey lacks suture openings on an end of the graft. Chuter teaches the use of openings 35 for sutures (fig. 1, for example) for the purpose of securing an end support to the graft and ultimately anchoring the prosthetic in an area with the best available tissue for anchorage. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized openings on the resultant combination device of Palmaz and Casey. A person of ordinary skill in the art would recognize that

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the reinforcement provided by openings 35 of Chuter would be desirable to prevent elongation or tears in the suture hole by providing a stronger location for attachment.

One of ordinary skill in the art would have further been motivated to provide suture openings to provide specific placement of sutures aid a surgeon in anchoring the prosthetic to a native blood vessel.

8. Chuter further teaches the use of at least one barb member 86 to provide further anchoring of the device. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the combination of Palmaz and Casey with at least one barb for the purpose of providing additional anchorage and stabilization of the device in the body. Chuter teaches at least one suture member integrally extending along a longitudinal axis of the device: see fig. 2 for example.

9. Claims **6-7, 9-10, 21-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) (Palmaz) in view of Casey, II et al. (Pub. No.: US 2004/0019375) (Casey) and Chuter et al. (Pub. No.: US 2003/0176912) (Chuter) as applied above, further in view of Kula et al (6,325,825 B1) (Kula) with supporting evidence from Moser (5725556).

10. Palmaz in combination with Casey and Chuter teaches an implantable medical graft as above. However the combination lacks the thickness of the undulating regions as less than that of the non-undulating regions. Kula teaches an implantable medical graft having thicker ends, which correspond to the non-undulating regions of Palmaz and Casey (col. 4, lines 60-66). It would have been obvious to one having ordinary skill

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in the art at the time the invention was made to combine the teaching of an implantable medical graft having thicker ends, as taught by Kula, to an implantable medical graft as per Palmaz and Casey, in order to “protect the artery and any plaque from abrasion that may be caused by the stent 10 ends during insertion of the stent 10. The modification also may provide increased radio-opacity at the ends of the stent 10. Hence it may be possible to more accurately locate the stent 10 once it is in place in the body” as found in Kula (col. 4, lines 60-66).

Regarding claim 7 Palmaz and Casey in further view of Kula fail to disclose the **specific** thicknesses of the claimed regions. However, Palmaz discloses that the thickness of the microperforated material is approximately 10 micrometers (page 21, lines 13-14). Palmaz also discloses that the circumferential corrugations may be formed by a “subtractive” method (Fig. 10). The reduction of the undulation region relative to the non-undulated region would result in a thickness of the thinner region *about* 3-7 micrometers.

11. With respect to claims 9, 10, 21 and 22 Palmaz, Casey, and Kula fail to disclose the suturing openings as cruciform, generally Y-shaped slots or elongated slots with a terminal fillet. However, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to make the slots these shapes. Applicant has not disclosed that these shapes provides an advantage, is used for a particular purpose, or solve a stated problem, and therefore appear to be a matter of obvious design choice. One of ordinary skill in the art, furthermore, would have expected Applicant’s invention to perform equally well with either the holes of Chuter or the claimed slots because both

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allow for the passage of sutures. Furthermore such shaped holes for sutures are known in the art (Moser U.S. Pat. No. 5725556). Therefore, it would have been obvious to one of ordinary skill in the art to modify the cited references to obtain the invention as specified in claims 9 and 10.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M- F (8am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, DAVID ISABELA, at 571-272-4749.*** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

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/S. G./

Examiner, Art Unit 3774

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774